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103D CONGRESS
2D SESSION

S. 2168

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the distribution of samples of prescription drugs.

IN THE SENATE OF THE UNITED STATES

JUNE 8 (legislative day, JUNE 7), 1994

Mrs. KASSEBAUM introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the distribution of samples of prescription drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE.

(A) SHORT TITLE.—This Act may be cited as the "Prescription Drug Marketing Reform Act of 1994".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. PROHIBITION OF DRUG SAMPLES.

Section 503 (21 U.S.C. 353) is amended—

(1) in the first sentence of subsection (c)(1), by inserting "distribute," after "No person may",

(2) in the second sentence of such subsection, by striking "and subsection (d)",

(3) by inserting after the second sentence of such subsection the following: "For purposes of this subsection, the term 'distribute' does not include providing a drug sample to enable a practitioner licensed to prescribe a drug subject to subsection (b) or a health care professional acting under the direction and supervision of such a practitioner to provide for the dispensing of or to dispense a sample of such drug if the sample is made available to a patient in accordance with regulations of the Secretary specifying conditions under which such drug is necessary for medical care.",

(4) in paragraph (2), by inserting "distribute," after "No person may",

(5) by redesignating paragraph (3) as paragraph (4) and by adding after paragraph (2) the following:

"(3) Nothing in paragraphs (1) and (2) precludes distribution of a drug subject to subsection (b) at no cost or nominal cost pursuant to a program established by the

manufacturer or distributor of such drug to provide it to specific identified patients who, for financial reasons, would not otherwise have access to such drug. The Secretary shall promulgate regulations to specify the documentation and record keeping required for such a program.", and

(6) by repealing subsection (d) and redesignating subsections (e), (f), and (g) as subsections (d), (e), and (f), respectively.

SEC. 3. ENFORCEMENT.

(a) PROHIBITED ACT.—Section 301(t) (21 U.S.C. 331(t)) is amended to read as follows:

"(t) the importation of a drug in violation of section 801(d)(1), the distribution, sale, purchase, or trade of a drug or drug sample or the offer to distribute, sell, purchase, or trade a drug or drug sample in violation of section 503(c), the distribution, sale, purchase, or trade of a coupon or the offer to distribute, sell, purchase, or trade such a coupon in violation of section 503(c)(2), or the distribution of drugs in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d).".

(b) PENALTY.—Section 303(b) (21 U.S.C. 333(b)) is amended—

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(1) in subparagraph (B), by inserting "distribute," after "knowingly",

(2) in subparagraph (C), by inserting "distributing," after "knowingly",

(3) in subparagraph (D), by striking "503(e)(2)(A)" and inserting "503(d)(2)(A)",

(4) in paragraph (5), by striking "because of the sale" through "503(c)(1)" and inserting "of a violation of section 503(c)", and

(5) by striking paragraphs (2), (3), and (4) and redesignating paragraph (5) as paragraph (2).

SEC. 4. EFFECTIVE DATE AND REGULATIONS.

The amendments made by this Act shall take effect upon the expiration of 180 days after the date of the enactment of this Act. During such 180 day period the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this Act. If final regulations are not promulgated before the expiration of such 180 days, the Secretary may not take any action to prevent a program, established before the expiration of such days, from providing a drug or a coupon for a drug to patients who would not otherwise be able financially to use such drug.

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